

May 6, 2010

John R. Bucher, Ph.D.
Associate Director
National Toxicology Program
P.O. Box 12233
Mail Drop K2-02
Research Triangle Park, North Carolina 27709

Re: NTP's Evaluation of Formaldehyde for the 12th Report on Carcinogens

Dear Dr. Bucher:

Dr. Jack Moore and I appreciated the opportunity to speak with you and Dr. Mary Wolfe on April 22 regarding certain aspects of the National Toxicology Program's current evaluation of formaldehyde for the 12th Report on Carcinogens. On behalf of Hexion Specialty Chemicals, Inc., ENVIRON International Corporation previously submitted written comments to NIEHS addressing a number of scientific issues that are critical to NTP's work in these regards.

As noted in our discussion with you and Dr. Wolfe, we request that, as NTP assesses the possible relation between formaldehyde exposures and cancer, NTP separately examine and assess the range of data for each of the three cancer types that NTP has identified -- i.e. nasopharyngeal cancer, sinonasal cancer, and myeloid leukemia. Moreover, we believe that NTP should clearly distinguish between these distinct cancer types both in arriving at scientific judgments and in creating written findings and reports. During our April 22 discussion we understood that you and Dr. Wolfe hold the same view regarding separate treatment and classifications for the three cancer types.

Evaluations of these three cancer types necessarily involve separate considerations of data that are relevant to each type. Thus, just as the evaluation of a chemical's possible role as a developmental toxicant necessitates an assessment (of relevant data) that is distinct from an assessment of the chemical's possible neurotoxic effects, so too do distinct types of tumors warrant separate assessments and corresponding cancer classifications.

In particular, we understand that NTP will make a single RoC listing decision for formaldehyde, and that formaldehyde will be listed in the highest category which NTP concludes is justified for at least one of the three cancer types. For example, if NTP concludes that formaldehyde is "known to be a human carcinogen" (NTP's first category) for cancer type #1, then formaldehyde will be listed in the RoC in this category. Moreover, this will be the case even if NTP concludes that the second listing category, "reasonably anticipated to be a human carcinogen", applies to cancer type #2 and/or #3.

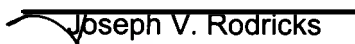
NTP has stated that it considers RoC listing decisions to be a matter of policy. That being the case, we request that, when it makes this policy determination for formaldehyde, NTP ensure that it (1) separately and transparently arrives at an RoC listing categorization for each of the three potential formaldehyde cancer types, and (2) thereafter determines the overall RoC listing for formaldehyde based upon the "highest" RoC category that is concluded for any one (or more) of these three cancer types. Not only is this approach fully grounded in sound scientific principles; it also will help ensure that NTP's reports and other statements are scientifically accurate and well-founded. This is especially pertinent at this time, because both the December 21, 2009 "Expert Panel Report (Part B) on Formaldehyde" and the "Draft Report on Carcinogens – Substance Profile for Formaldehyde" (published by NTP on April 21, 2010) do not reflect and make clear these distinctions. Rather, each of these reports arrives at a single, overall RoC listing decision that appears to apply indiscriminately to all three cancer types, without separate, type-specific RoC categorizations (to include corresponding justifications).

We request NTP to ensure that this approach is followed throughout the remainder of the current review of formaldehyde for the 12th RoC, and is reflected in all reports and other written materials prepared in support of that review and the NTP's final listing decision.

Further, because of the impending peer review by members of the Board of Scientific Counselors, we request that you promptly make this letter available to all BSC members.

Thank you again for speaking with us and considering these points. Please contact me (at 703-516-2316) with any comments or questions that you have.

Sincerely yours,
[Redacted]


Principal

cc: Dr. Linda Birnbaum, NTP
Dr. Ruth Lunn, NTP
Dr. Jack Moore
Dr. Mary Wolfe, NTP